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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/522,217 03/09/00 NOVAK

J 99-16

HM12/0108

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EXAMINER

SEHARASEYON, J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 01/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/522,217	Applicant(s) NOVAK ET AL.	
	Examiner Jegatheesan Seharaseyon	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. This application does not contain claim 41 but does contain claims 42 and 43. Under Rule 26, these claims have been renumbered 41 and 42 respectively.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 are drawn to a protein, classified in class 530, subclass 350.
- II. Claims 10-12 are drawn to a fusion protein, classified in class 530, subclass 387.3.
- III. Claims 13-24 are drawn to a nucleic acid encoding a protein, a vector, cell culture and a process for producing the protein, classified in class 435, subclass 69.1.
- IV. Claims 25-27 are drawn to a method of producing an antibody to a α 11 ligand polypeptide and an anti- α 11 ligand antibody classified in class 435, subclass 7.1.
- V. Claims 28-30 and 40 are drawn to a method of stimulating an immune response in a mammal classified in class 424, subclass 143.1.
- VI. Claims 31-34 are drawn to a method for expansion of hematopoietic cells, classified in class 424, subclass 577.
- VII. Claims 35-38 are drawn to a method of reducing proliferation of neoplastic B or T cells using a composition of α 11 ligand, classified in class 424, subclass 573.

- VIII. Claim 39 is drawn to a method of reducing proliferation of neoplastic B or T cells using ligand/toxin fusion protein, classified in class 424, subclass 573.
- IX. Claim 41 is drawn to a method of detecting the presence of α 11 ligand RNA, classified in class 435, subclass 6.
- X. Claim 42 is drawn to a method of detecting the presence of α 11 ligand, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other, for the following reasons:

Inventions (I and II) and III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The polynucleotide of invention III can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of inventions II and III can be used as a probe or used therapeutically or diagnostically, e.g. in screening.

Inventions (I and II) and III are related as product made and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein can be prepared by materially different process, such as by chemical synthesis.

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Inventions (I and II) and IV-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of inventions I and II can also be used in assays for the identification of agonoist and antaganoists of the polypeptide.

Inventions III and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention II can also be used in the production of protein of interest.

Inventions IV and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention III can also be used to obtain the polynucleotide of invention II, and can be used in diagnostics.

Inventions III and IV-VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions IV-X are independent and distinct, each from the other, because the methods are practiced with materially different starting materials, have materially different process steps, and are for materially different purposes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

If applicant elects Group II, he/she must also elect a species set forth in claims 10 and 11 from each of group of the peptides set forth in each of "a first polypeptide", "a second polypeptide", "a third polypeptide", and "a forth polypeptide". Specifically, applicant is required to choose one of (a)-(e) from each of the polypeptides. The claims of this group will be examined to the extent of the elected species. If applicant elects Group IV, he must also elect from claim 25, a species of (a)-(p). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 10,11 and 25 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered non responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

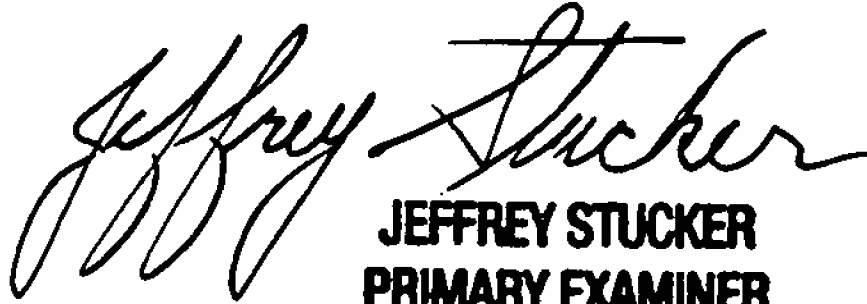
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

js
January 4, 2001


JEFFREY STUCKER
PRIMARY EXAMINER